Complete Summary

GUIDELINE TITLE

Acute onset flank pain, suspicion of stone disease.

BIBLIOGRAPHIC SOURCE(S)

Baumgarten DA, Francis IR, Bluth EI, Bush WH Jr, Casalino DD, Curry NS, Israel GM, Jafri SZ, Kawashima A, Papanicolaou N, Remer EM, Sandler CM, Spring DB, Fulgham P, Expert Panel on Urologic Imaging. Acute onset flank pain, suspicion of stone disease. [online publication]. Reston (VA): American College of Radiology (ACR); 2007. 5 p. [45 references]

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previous published version: Rosenfield AT, Choyke PL, Bluth E, Bush WH Jr, Casalino DD, Francis IR, Jafri SZ, Kawashima A, Kronthal A, Older RA, Papanicolaou N, Ramchandani P, Sandler C, Segal AJ, Tempany C, Resnick MI, Expert Panel on Urologic Imaging. Acute onset flank pain, suspicion of stone disease. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 4 p. [32 references]

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

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SCOPE

DISEASE/CONDITION(S)

Acute onset of flank pain, suspicion of stone disease

GUIDELINE CATEGORY

Diagnosis
Evaluation

CLINICAL SPECIALTY

Emergency Medicine
Family Practice
Internal Medicine
Nephrology
Obstetrics and Gynecology
Radiology
Urology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of radiologic examinations for patients with acute onset flank pain or suspected urinary tract stones (calculi)

TARGET POPULATION

Patients with suspected ureteral stones who present with acute onset flank pain

INTERVENTIONS AND PRACTICES CONSIDERED

1. Computed tomography (CT) of the abdomen and pelvis without contrast
2. X-ray intravenous urography
3. Doppler ultrasound (US) of the kidney, ureters and bladder (KUB)
4. Magnetic resonance imaging (MRI) of the abdomen and pelvis
5. X-ray of the abdomen

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in evaluating patients with suspected ureteral stones who present with acute onset flank pain

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of peer-reviewed medical journals, and the major applicable articles were identified and collected.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed for reaching agreement in the formulation of the appropriateness criteria. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi technique to arrive at consensus. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed

after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by the Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible. If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not performed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Acute Onset Flank Pain

Variant 1: Suspicion of stone disease.

Radiologic Procedure	Rating	Comments	RRL*
CT abdomen and pelvis without contrast	8	Reduced-dose techniques preferred.	High
X-ray intravenous urography	7		Low
US kidney with	6	Preferred exam in pregnancy, in	Low

Radiologic Procedure	Rating	Comments	RRL*
Doppler and KUB		patients who are allergic to iodinated contrast, and if NCT is not available.	
MRI abdomen and pelvis	4	MR urography technique should be performed. See comments regarding contrast in text under "Anticipated Expectations."	None
X-ray abdomen	1	Most useful in patients with known stone disease.	Low
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Recurrent symptoms of stone disease.

Radiologic Procedure	Rating	Comments	RRL*
CT abdomen and pelvis without contrast	7	Reduced dose techniques preferred.	High
US kidney with Doppler and KUB	7		Low
X-ray abdomen	6	Good for baseline and follow-up post treatment.	Low
X-ray intravenous urography	2		Low
MRI abdomen and pelvis	2		None
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Urinary tract stones (calculi) are thought to result from either excessive excretion or precipitation of salts in the urine or a relative lack of inhibiting substances. Men are more commonly affected than women, and the incidence increases with age until age 60. Blacks and children are affected less frequently. Renal calculi tend to be recurrent, and flank pain is a nonspecific symptom that may be associated with other entities; therefore, evaluation with imaging is recommended at the initial presentation.

A renal calculus small enough to pass into the ureter may cause blockage of urine flow with distension of the upper urinary tract. Ureteral hyperperistalsis occurs, resulting in acute onset of sharp, spasmodic flank pain and hematuria. The ureter contains several areas where calculi commonly become lodged, (e.g., at the ureteropelvic junction), the iliac vessels, and the ureterovesical junction. The probability of spontaneous passage of a ureteral calculus measuring 5 mm in axial diameter or less is very high. A 10 mm calculus, however, is very unlikely to pass spontaneously. Therefore, the treating physician wants to know the size of the calculus as well as its location and its effect on renal function.

Patients with a suspected diagnosis of renal colic have traditionally been evaluated with urinalysis, plain abdominal radiography (KUB), or excretory urography, commonly referred to as intravenous pyelogram (IVP). More recently, ultrasonography (US), computerized tomography (CT), and magnetic resonance imaging (MRI) have been used.

Radiography

The plain-film of the abdomen may be sufficient to diagnose ureterolithiasis in patients with known stone disease and previous KUBs. The sensitivity of the KUB for ureterolithiasis in other patients is poor. Studies by some researchers found sensitivities of 62% and 58% when the radiographs were interpreted retrospectively. One study correlated the KUB with noncontrast CT (NCT) retrospectively, so that an exact correlation was made between stones on the CT scan and the calcific density on the KUB. A sensitivity of only 59% was found for detecting ureteral calculi on the KUB. Another study used the KUB as a guide for US evaluation of flank pain. They found 64% sensitivity for detecting ureteral calculi and had 6 false positive cases among the 66 patients evaluated. While the KUB may be a valuable part of the IVP or US evaluation of flank pain, it has a very limited role when used alone, and it should not be used to triage which patient should receive NCT.

Computed Tomography

Since the introduction of the use of helical (spiral) NCT as the initial study in evaluating flank pain numerous investigations have confirmed it to be the study with the highest sensitivity (95%-96%) and specificity (98%) for ureterolithiasis. Virtually all stones are radio-opaque, and stone size can be measured accurately in cross section, aiding in predicting outcome. Stone location, accurately depicted by NCT, has also been associated with spontaneous stone passage rates, with the more proximal stones having a higher need for intervention. Recently, coronal reconstruction of axial CT scans have been shown to more accurately predict stone size in the craniocaudad direction, although this dimension is not critical to estimating the likelihood of stone passage. The degree of perinephric stranding

present on the affected side on NCT has also been shown to correlate inversely with the likelihood of stone passage, giving additional prognostic information, but this finding has been disputed in other studies.

The amount of stranding is related to the time after onset of pain and is usually not seen in the first 2 hours following the onset of flank pain. It may take up to 8 hours after the onset of pain to become maximal. Secondary signs such as ureteral dilatation and perinephric stranding allow CT to make a diagnosis of a recently passed stone.

NCT has been directly compared with the IVP in three series. NCT was equal to the IVP in diagnosing obstruction and more reliable in diagnosing the presence of nephrolithiasis. NCT is also reliable for diagnosing flank pain due to causes other than ureterolithiasis such as appendicitis, diverticulitis, and torsed ovarian masses. NCT is safer than the IVP since it uses no contrast media, is rapid (with the entire study taking minutes), and does not require the technical expertise that US does. When CT is available, it is the best first study in the nonpregnant adult presenting with flank pain likely to be due to stone disease and has been shown to be more cost effective.

Concerns over radiation exposure, especially in young stone patients, have led to the development and evaluation of reduced dose regimens. Other recent technique refinement has included evaluation of the effect of slice width and overlapping image reconstruction on stone detection.

Intravenous Pyelography

The IVP is the previous standard study for ureterolithiasis and is still the best investigation if NCT is not available. It provides information regarding site and degree of obstruction, size of stone, and effect of obstruction on renal excretion. This examination has a number of relative contraindications, including renal insufficiency, dehydration, past reaction to iodinated contrast agents, and pregnancy. The availability of nonionic iodinated contrast material has reduced the risk of reaction. It may take several hours for excretion to occur in the presence of acute obstruction, in which case it is more time consuming than the alternative techniques. Another disadvantage is the inability of the IVP to identify alternative diagnoses.

Ultrasound

US is a safe, noninvasive imaging modality that can be used to study the urinary tract effectively. The diagnosis of obstructive urinary tract calculi depends on identification of the offending calculus and concomitant pelvicaliectasis and ureterectasis extending to the obstructing site. Because it may take many hours for pelvicaliectasis and ureterectasis to develop, US reportedly will miss over 30% of acute obstructions caused by an uretheral stone in patients who are not specifically hydrated for the study. Two studies detected hydronephrosis in 7 of 20 patients (35%) and 16 of 22 patients (73%), respectively, nonhydrated patients with uretheral calculi. More recently, US has been found to be 100% sensitive for signs of obstruction (hydronephrosis, ureteral dilatation, and/or perirenal fluid) perhaps indicating improvement in US equipment. The use of intrarenal Doppler

US improves the detection of early obstruction by evaluating for elevated resistive index (RI) in kidneys with nondilated collecting systems.

Since KUB is superior to US in detecting ureteral calculi, one study recommended a combination of KUB and US. US in these cases is used to detect ureteropyelocaliectasis and then to trace the dilated ureter to a shadowing stone. US can also evaluate the presence and type of ureteral jet (with obstruction the jets are absent, diminished significantly in frequency or a constant slow trickle). In a series of 180 patients, the authors showed a 95% negative predictive value of the KUB/US combination, indicating that IVP was not likely to be helpful if the KUB/US tests are negative. However, IVP was indicated if the KUB/US combination was equivocal or if interventional treatment was anticipated.

One group of researchers also performed a comparison of KUB, US, combination of KUB/US, and IVP in 49 patients. The accuracies of KUB (61%) and US (69%) were lower than that of IVP (92%). The accuracy of the combination of KUB/US was 71%, still lower than that of IVP. In an effort to reduce the number of IVP examinations needed, a model was tested in which only patients with negative US results went on to have an IVP. This algorithm showed 93% sensitivity and 79% specificity. The KUB/US combination has also been compared to NCT. In this prospective study of 66 patients, the KUB/US combination had a sensitivity of 79% (vs. 93% for NCT) for detecting ureteral stones. All missed cases had spontaneous stone passage, leading the authors to conclude that after a negative KUB/US combination, NCT would not add useful information. They suggest use of NCT in those who fail to respond to conservative management or in those in whom surgery is anticipated. The advantage of US is its lack of ionizing radiation and its ability to show some calculi. For this reason it has been suggested for evaluating stones in pregnant women. Its disadvantages include the need for skilled personnel, its inability to accurately measure the size of the calculus, the need to observe the ureteral jet phenomenon at the ureterovesical junction, and its inability to differentiate dilatation without obstruction from true obstruction.

Magnetic Resonance Imaging

One study applied magnetic resonance urography (MRU) to the evaluation of 23 patients with acutely obstructed kidneys. They found 100% sensitivity for diagnosing obstruction, with perirenal fluid seen in 21 of 23 obstructed kidneys (87%) and in no normal kidneys. The site of the obstruction was seen in 80% of these obstructed kidneys. Round signal voids corresponding to the location of stones on correlative IVPs were seen in 12 of 18 patients with ureteric obstruction caused by a stone. These appearances were nonspecific and were also seen secondary to blood clot or tumor. Another study examined 60 patients with obstructive uropathy. In the 13 patients with ureteric stones, MRU correctly identified the site of obstruction in 12 (1 stone moved between the MRU and confirmatory imaging). Forty-six percent of the stones were seen as signal voids against a background of bright urine on T2-weighted images. MRU has been successfully used in pregnant patients with flank pain.

Recurrent Symptoms of Stone Disease

In addition to pregnant patients, the patient with known stone disease and recurrent symptoms also presents a challenge. In this setting, the likelihood of

stone disease as the cause of flank pain is higher, but repeated NCTs raise a concern about excessive radiation exposure. One group of researchers examined the issue of radiation exposure associated with repetitive NCT in this setting. In a 6-year period, 5,564 NCTs were performed for renal colic. While the vast majority of patients (96%) underwent 1 or 2 NCTs with an estimated effective dose of 6.5-17 mSv, 176 patients had three or more NCTs with an estimated dose of 20-154 mSv. One patient had 18 NCTs over the 6- years! In this setting, every effort should be made to use low-dose NCT. A recent study found excellent sensitivity (95%) and specificity (97%) for detecting stones with a low-dose protocol (30 mA) compared to a standard-dose protocol (180 mA) in patients with a body mass index (BMI) of <30. Further, if the patient has persistence of symptoms from a documented stone and repeat imaging is contemplated, a limited NCT of the area of the stone through the bladder could be considered if stone passage is the main question. Alternatively, if the stone can be seen by KUB, a repeat KUB might provide useful information at a much lower dose.

Anticipated Exceptions

NCT is the most rapid and accurate technique for evaluating flank pain. If there is uncertainty about whether a calcific density represents a ureteral calculus or a phlebolith, contrast medium can be injected and the scan repeated for definitive diagnosis. The IVP, which is readily available and is familiar to nonradiologic physicians, is the technique of choice if CT is not available. In pregnant patients with flank pain, US is the best initial study. While a limited IVP has been used to evaluate flank pain in pregnancy when the US study is not diagnostic, MRU has potential utility in diagnosing acute urinary tract obstruction without the use of ionizing radiation. NCT using an ultra-low-dose protocol could also be considered.

Nephrogenic systemic fibrosis (NSF, also known as nephrogenic fibrosing dermopathy) was first identified in 1997 and has recently generated substantial concern among radiologists, referring doctors and lay people. Until the last few years, gadolinium-based MR contrast agents were widely believed to be almost universally well tolerated, extremely safe and non-nephrotoxic, even when used in patients with impaired renal function. All available experience suggests that these agents remain generally very safe, but recently some patients with renal failure who have been exposed to gadolinium contrast agents (the percentage is unclear) have developed NSF, a syndrome that can be fatal. Further studies are necessary to determine what the exact relationships are between gadolinium-containing contrast agents, their specific components and stoichiometry, patient renal function and NSF. Current theory links the development of NSF to the administration of relatively high doses (e.g., >0.2 mM/kg) and to agents in which the gadolinium is least strongly chelated. The FDA has recently issued a "black box" warning concerning these contrast agents (http://www.fda.gov/cder/drug/InfoSheets/HCP/gcca_200705HCP.pdf).

This warning recommends that, until further information is available, gadolinium contrast agents should not be administered to patients with either acute or significant chronic kidney disease (estimated GFR <30 mL/min/1.73m^2), recent liver or kidney transplant or hepato-renal syndrome, unless a risk-benefit assessment suggests that the benefit of administration in the particular patient clearly outweighs the potential risk(s).

Abbreviations

- CT, computed tomography
- KUB, kidneys, ureters, bladder
- MR, magnetic resonance
- MRI, magnetic resonance imaging
- NCT, noncontrast computed tomography
- US, ultrasound

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate radiologic examinations for patients with acute onset of flank pain or suspected urinary tract stones (calculi)

POTENTIAL HARMS

- The relative radiation level is high for computed tomography (CT) of the abdomen and pelvis without contrast.
- There is the potential for adverse reaction to iodinated contrast media.
- Some patients with renal failure who have been exposed to gadolinium contrast agents (the percentage is unclear) have developed nephrogenic systemic fibrosis (NSF), a syndrome that can be fatal.

CONTRAINDICATIONS

CONTRAINDICATIONS

Relative contraindications to intravenous pyelogram (IVP) include renal insufficiency, dehydration, past reaction to iodinated contrast agents, and pregnancy.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Baumgarten DA, Francis IR, Bluth EI, Bush WH Jr, Casalino DD, Curry NS, Israel GM, Jafri SZ, Kawashima A, Papanicolaou N, Remer EM, Sandler CM, Spring DB, Fulgham P, Expert Panel on Urologic Imaging. Acute onset flank pain, suspicion of

stone disease. [online publication]. Reston (VA): American College of Radiology (ACR); 2007. 5 p. [45 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1995 (revised 2007)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Urologic Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Deborah A. Baumgarten, MD, MPH; Isaac R. Francis, MD; Edward I. Bluth, MD; William H. Bush, Jr., MD; David D. Casalino, MD; Nancy S. Curry, MD; Gary M. Israel, MD; S. Zafar H. Jafri, MD; Akira Kawashima, MD; Nicholas Papanicolaou, MD; Erick M. Remer, MD; Carl M. Sandler, MD; David B. Spring, MD; Pat Fulgham, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previous published version: Rosenfield AT, Choyke PL, Bluth E, Bush WH Jr, Casalino DD, Francis IR, Jafri SZ, Kawashima A, Kronthal A, Older RA, Papanicolaou N, Ramchandani P, Sandler C, Segal AJ, Tempany C, Resnick MI, Expert Panel on Urologic Imaging. Acute onset flank pain, suspicion of stone disease. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 4 p. [32 references]

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

ACR Appropriateness Criteria® *Anytime*, *Anywhere*™ (PDA application). Available from the ACR Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.
- ACR Appropriateness Criteria®. Relative radiation level information. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 6, 2001. The information was verified by the guideline developer as of June 29, 2001. This summary was updated by ECRI on September 7, 2004. The updated information was verified by the guideline developer on October 8, 2004. This summary was updated by ECRI on February 7, 2006. This NGC summary was updated by ECRI Institute on November 14, 2007.

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